DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

February 6, 2002

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Refer to MIN 02 – 22

Alberto Martinez, Jr., M.D.
Senior Vice President and General Manager
Aventis Bio-Services, Inc.
102 First Avenue
King of Prussia, Pennsylvania 19406

Dear Dr. Martinez:

During an inspection of Aventis BioServices, Inc., located at 2111 West North Avenue, Milwaukee, WI, between December 12 and 19, 2001, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act and Title 21, Code of Federal Regulations, Parts 600-680 (21 CFR 600-680), as follows:

1. Failure to maintain complete and accurate records from which unsuitable donors may be identified so that products from such individuals will not be distributed [21 CFR 606.160(e)], in that:

    •   Current donor cards were found in the Rolodex files for donors that tested positive for viral markers. According to your procedures, current donor cards are to be replaced with deferred donor cards during deferral process to prevent future donations at this center and at other local centers.

2. Failure to maintain and/or follow adequate written standard operating procedures [21 CFR 606.100(b)], in that:

    •   Donation histories are not always documented in donor record file within 24 hours (for example, donor ▓▓▓▓▓▓▓▓on 5/10/01, 5/21/01, and 5/23/01).

- QAS or designee does not always review all completed Daily Donor Check Log and Donor Record Files within three business days to assure all information has been properly recorded, all forms are completed and required action has been taken with all donors (for example, donors ▮▮▮▮▮ on 5/10/01, 5/21/01, and 5/23/01, and donor▮▮▮▮▮ on 7/31/01).

- One phlebotomy scrub for less than 30 seconds was observed and another did not work in a circular pattern with second applicator.

3. Failure to adequately determine equipment shall perform in the manner for which it was designated, and observe, standardize, and calibrate as prescribed in your procedures [21 CFR 606.60(a)], in that:

- Two freezer alarm activation temperature checks conducted on 2/9/01, 8/9/01, and 12/14/01 showed no response was received by *nnn* alarm notification service. Your procedure states response must be received within 15 minutes. Second alarm check on 8/9/01 showed response time of 50 minutes. No investigation was conducted to determine the cause of the failed alarm checks and no corrective actions were taken.

4. Failure to maintain disposition records [21 CFR 606.160(b)(3)(i)], in that:

- No destruction record completed for 34 units listed on Unacceptable Plasma Record. These units were collected during December 2000, January 2001, and February 2001.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all requirements of Federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.
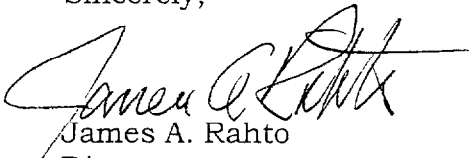
We are very concerned about the apparent lack of cGMP oversight at your facility. We believe it is prudent to meet to discuss your plans for correction and we have scheduled a meeting at our Milwaukee Resident Post, 2675 No. Mayfair Road, Suite 200, Milwaukee, WI, on February 27, 2002, at 9:00 a.m. Contact

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Alberto Martinez, Jr., M.D.
February 6, 2002

Compliance Officer Judy Heisick at the Minneapolis District Office, (612) 334-4100, ext. 161, if you need to reschedule. Please be prepared to discuss your corrective actions.

Sincerely,

James A. Rahto
Director
Minneapolis District

JEH/ccl

xc: Paul Smith
     Director of Operations and
          Designated Authorized Official
     Aventis Bio-Services, Inc.
     180-A Market Place
     Knoxville, TN 37922